Endoscopic surveillance using narrow-band imaging in patients with hyperplastic polyposis syndrome (HPS): A multicentre cohort study

Published: 20-09-2010
Last updated: 03-05-2024

To prospectively compare NBI with HRE for the detection and differentiation of polyps in HPS in a large multicentre HPS cohort (n~125).

Ethical review	-
Status	Pending
Health condition type	Gastrointestinal tract disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON34162

Source
ToetsingOnline

Brief title
ECLIPSE

Condition

- Gastrointestinal tract disorders congenital

Synonym
polyps, tumor

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: endoscopic, Hyperplastic, NBI, polyp

Outcome measures

Primary outcome

1) Polyp miss-rates of NBI vs. HRE

2) The diagnostic accuracy of NBI-VPI vs. HRE-VPI for the differentiation of

polyps

Secondary outcome

none

Study description

Background summary

Hyperplastic polyposis syndrome (HPS) is characterized by the presence of multiple colorectal serrated polyps and co-existent conventional adenomas and is associated with an increased colorectal cancer (CRC) risk. Considering the presumed increased risk of malignant progression of polyps in HPS, detection and removal of polyps seems necessary to prevent CRC development in these patients. In HPS however, serrated polyps, which are the overall majority, are generally small in size, flat in shape and unremarkable in colour. These features are associated with polyp miss-rates of up to 26% using standard colonoscopy. Narrow-band imaging (NBI) may improve the detection and differentiation of these polyps. In a recent randomized cross-over study from our group, comparing NBI with standard white-light endoscopy (HRE) for the detection of polyps in HPS, we demonstrated that NBI had a significantly lower polyp miss-rate than HRE (10% versus 36%; OR 0.21; p<0.001) in HPS 1. However this pilot study was performed by a single endoscopist in one academic centre. To confirm these findings, a subsequent multi-centre study involving more patients and multiple endoscopists is required.

Study objective

To prospectively compare NBI with HRE for the detection and differentiation of polyps in HPS in a large multicentre HPS cohort (n~125).

Study design

All HPS patients will be invited to undergo tandem colonoscopy with HRE and NBI for their first prospective screening round or their annual prospective surveillance colonoscopy. All individuals will be prepared with 4 litre Poly Ethylene Glycol solution (Kleanprep) or 2 liters PEG (Moviprep) with an additional 2 liters of fluids. All procedures will be performed under conscious sedation with midazolam and/or fentanyl, according to current clinical practice. Cecal intubation is confirmed by identification of the appendiceal orifice and ileocecal valve.
Subsequently, each colonic segment (ascending, transverse, descending and recto sigmoid colon) will be inspected twice; by both HRE and NBI. The order of the two techniques will be determined by the randomization procedure. During the withdrawal phase, each segment of the colon will be meticulously inspected for the presence of lesions of 3mm in size and larger. When lesions are found they will be classified according to the shape (Paris classification).49 In addition, the size (estimated by an opened biopsy forceps which measures 8 mm), localization (part of colon and distance from the anus), predicted histology of each lesion and VPI with NBI and with HRE will be recorded. Subsequently, digital still images of the lesion with both imaging modes (HRE and NBI) will be taken. Immediately after these images are taken, the lesion will be removed. After having inspected a segment with the first imaging modality and removal of all detected lesions by the first technique, the endoscope is advanced again to the beginning of the colonic segment and the other mode will be used for the second inspection of the same segment. If new lesions are found, the above mentioned polyp characteristics will be recorded before removal of the lesions. A maximum time of approximately 1.5 hours will be used for the endoscopic procedure; otherwise examination times become too long and the procedure becomes too inconvenient for the patient. One investigator or research nurse will be present during the procedure to collect procedure data using a case record form.

Study burden and risks

The endoscopic procedure in this study is comparable to the standard procedure for regular patient care except that each segment of the colon will be inspected twice, which may lead to increasing the procedural time with about 15 minutes. Increasing the procedural time does not increase the risk of complications. The risk of a diagnostic colonoscopy is minimal (< 1%)

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients presenting, or under surveillance at the endoscopy department of the AMC with:
1) > 20 HPs found at colonscopy, or
2) > 5 HPs proximal to the sigmoid colon, or
3) Any number of HPs occuring proximal to sigmoid colon in an individual who has a first-degree relative with HPs

Exclusion criteria

1) History of inflammatory bowel disease 2) severe coagulopathy 3) age less than 18 years and 4) insufficient bowel preparation (< 90% of colonic mucosa visible)

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2010
Enrollment:	72
Type:	Anticipated

Ethics review

Not available

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL32834.018.10